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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,472	11/14/2003	Charles A. Vacanti	07917-082003	1928

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EXAMINER

GAMETT, DANIEL C

ART UNIT PAPER NUMBER

1647

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/713,472	VACANTI ET AL.	
	Examiner	Art Unit	
	Daniel C. Gamett, PhD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43,44 and 54-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43,44 and 54-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendments of 01/10/2006 have been entered in full. Claims 1-42 and 45-53 are cancelled. Claims 43, 44, and 54-58 are under examination.
2. All prior objection/rejections not specifically maintained in this office action are hereby withdrawn.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

35 U.S.C. § 102

4. Rejection of claims 43 and 44 under 102(b) as being anticipated by Cornelius *et al.* is maintained, and hereby extended to include claims 54 and 57. Claims 43 and 44 are product-by-process claims in which the product is a population of undifferentiated cells; claim 44 specifies that the cells are isolated from pancreas or adrenal gland tissue. Claims 54 and 57 add limitations to the process. In product-by-process claims, the burden is on Applicant to establish that the claimed process imparts a physically distinct characteristic on the product, such that it is materially different from the prior art product. The stem cells isolated by Cornelius *et al.* are a population of undifferentiated cells isolated from the pancreas.

New Rejections Necessitated by Applicant's Amendment

Claim Rejections - 35 USC § 102

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5. Claims 43 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 3039932, June 19, 1962. The claim is drawn to an undifferentiated cell population isolated from the pituitary. The '932 patent teaches isolation of cells from the anterior pituitary by trypsin digestion followed by centrifugation (column 3, lines 57-72). The cells thus isolated would inherently possess all of the characteristics of the cell population of the instant claim, as the source and method of isolation are the same.

Claim Rejections - 35 USC § 112

6. Claims 43, 44, and 54-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for initial steps that may lead to isolation of neuroendocrine undifferentiated cells known from prior art to be present in adult pancreas, does not reasonably provide enablement for an isolated neuroendocrine undifferentiated cell population from adult other tissues or organs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. Claim 43 is drawn to a mammalian adult neuroendocrine undifferentiated cell population. Dependent claims 44, 55, and 56 specify that the undifferentiated cell population is isolated from adrenal gland or pancreas tissue (claim 44), hypothalamus, pituitary, parathyroid or thyroid (claim 55) or intestinal tract or aorta (claim 56.) Dependent claims 54 and 57 add technical limitations to the isolation procedure and in claim 58 the cell population further comprises a hydrogel support structure. For guidance, the specification provides Example 9, wherein adrenal gland

and pancreas tissues were digested with trypsin and cells were separated from buffer by centrifugation. The procedure described in example 9 would be expected to yield a mixed population of cells. Given the source tissues, one of skill in the art would accept that the mixed population of cells probably comprises neuroendocrine cells and that some of the cells in the population are undifferentiated. The specification does not, however, teach whether any of the isolated cells are both undifferentiated and neuroendocrine. The specification directs the skilled artisan toward small, round cells, of which there are “many” (p. 52, lines 12-14); the small round cells are undifferentiated in that they do not display any obvious characteristics of a differentiated cell type, but the specification does not demonstrate that these cells are neuroendocrine, i.e. capable of secreting a neurotransmitter or hormone, or that they are capable of differentiating into a neuroendocrine cell. The specification does not teach that cells isolated from any other tissue even resemble the cells minimally characterized in Example 9. In the case of intestinal tract or aorta (claim 56), the neuroendocrine component of these tissues derives only from the fact that they are innervated (see Specification, page 26, lines 7-11), and so the fraction of undifferentiated neuroendocrine cells in a mixed population of trypsin-digested tissue would be expected to be much lower than in the adrenal gland and pancreas tissues of Example 9.

7. Due to the large quantity of experimentation necessary to determine if a population of cells comprises neuroendocrine undifferentiated cells, the lack of direction/guidance presented in the specification regarding the neuroendocrine characteristics of the isolated cells, for their capacity to differentiate, or for their presence in various tissues, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art

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which established the unpredictability of finding neuroendocrine undifferentiated cells in various tissues, especially those in which the neuroendocrine component derives only from innervation, and the breadth of the claims which fail to recite functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Conclusion

8. No claims are allowed.
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, Ph.D., whose telephone number is 571 272 1853. The examiner can normally be reached on M-F, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DCG

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27 March 2006

Daniel C Gamett
DANIEL C. GAMETT
PRIMARY EXAMINER